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Amendment and Response

Serial No.: 10/027,226 Confirmation No.: 9039 Filed: 20 December 2001

For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL

MIXTURES USING A HYDROPHILIC SOLID SUPPORT IN A HYDROPHOBIC MATRIX

### Remarks

The Office Action mailed 27 July 2004 has been received and reviewed. Claims 1, 20, 26, 28, 47, 50, and 78 having been amended, and claims 68-76 having been canceled herein, the pending claims are claims 1, 3-28, 30-55, 62-67, and 77-78. Claims 1, 3-28, and 30-49 having been withdrawn from consideration, the claims currently under examination are claims 50-55, 62-67, and 77-78.

The language "at least partially embedded" (i.e., partially or fully embedded) in claims 1, 20, 26, 28, 47, 50, and 78 has been amended by deleting the words "at least," so as to recite "particles of a hydrophilic solid support partially embedded within a hydrophobic matrix" (e.g., claims 1, 26, 28, and 50) or "hydrophilic particles disposed on a layer of a hydrophobic matrix and partially embedded therein" (e.g., claims 20, 47, and 78).

Reconsideration and withdrawal of the rejections are respectfully requested.

#### Objections to the Claims

The Examiner objected to claims 68-77 under 37 C.F.R. §1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Specifically, the Examiner alleged that dependent claims 68-77 recite language directed to material tested in the devices, which would also be an intended use that would be given no patentable weight during examination. Applicants respectfully disagree. However, in the interest of expediting prosecution of the present application, claims 68-76 have been canceled. Thus, claim 77 remains the only claim objected to by the Examiner.

Claim 77 recites further language directed to the device (i.e., "the device is a microfluidic device"). Thus, claim 77 does not recite language directed to material tested in the device.

Therefore, Applicants respectfully submit that claim 77 is in proper dependent form.

Reconsideration and withdrawal of the objection to the claims is respectfully requested.

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# Provisional Obviousness-Type Double Patenting Rejection

Claims 50-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-58 of copending Application No. 10/417,609 in view of Dusterhoft et al. (U.S. Patent No. 6,451,260). Further, claims 50-53 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39-42 of copending Application No. 10/272,222 in view of Dusterhoft et al. (U.S. Patent No. 6,451,260). Applicants note that although the Examiner based the second rejection on Application No. 10/272,222, the rejection in the Office Action mailed 7 January 2004 was based on Application No. 10/027,222. In the event the rejection is maintained, clarification is respectfully requested.

Upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Applicants will provide an appropriate response. In the event that the provisional obviousness-type double patenting rejections are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

#### Rejections under 35 U.S.C. §103

The Examiner maintained the rejection under 35 U.S.C. §103(a) of claims 50-52, 64-65, and 68-77 as being unpatentable over Nelson et al. (U.S. Patent No. 6,344,326) in view of Dusterhoft et al. (U.S. Patent No. 6,451,260); claim 53 as being unpatentable over Nelson et al. and Dusterhoft et al. as applied above, and further in view of Mian et al. (U.S. Patent No. 6,319,469); claims 54-55 and 66-67 as being unpatentable over Nelson et al. and Dusterhoft et al. as applied above, and further in view of Chisolm et al. (U.S. Patent No. 4,399,009); claims 62-63 as being unpatentable over Nelson et al. and Dusterhoft et al., and further in view of Kellogg et

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al. (U.S. Patent No. 6,632,399). Claims 68-76 having been canceled and claims 50 and 78 having been amended, Applicants respectfully traverse the rejection.

"To establish a prima facie case of obviousness... the prior art reference (or references when combined) must teach or suggest all the claim limitations." M.P.E.P. §706.02(j). Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness.

Independent claim 50 (as amended) recites a device that includes a solid-phase extraction material including particles of a hydrophilic solid support partially embedded within a hydrophobic matrix. Nelson et al. and Dusterhoft et al. were both discussed in the Amendment and Response submitted by Applicants on October 3, 2003, and the discussion is incorporated herein by reference. Specifically, Dusterhoft et al. disclose that "the resin preferably comprises both hydrophilic and hydrophobic segments within its molecules" (column 10, lines 30-31). However, Applicants respectfully submit that neither Nelson et al. nor Dusterhoft et al. teach or suggest particles of a hydrophilic solid support partially embedded within a hydrophobic matrix (e.g., claim 50, as amended). Thus, Applicants respectfully submit that the Examiner has failed to establish a prima facie case of obviousness.

However, the Examiner further pointed to column 11, line 41 through column 12, line 15, which discloses that "[a]nother type of granular microparticles consists of an inorganic core such as microporous silica gel with a microlayer of organic polymer" (column 11, lines 48-50). However, Applicants respectfully submit that Dusterhoft et al. fail to disclose or suggest a device that includes "particles of a hydrophilic solid support partially embedded within a hydrophobic matrix" (e.g., claim 50 as amended, emphasis added) or "hydrophilic particles disposed on a layer of a hydrophobic matrix and partially embedded therein" (e.g., claim 78 as amended, emphasis added).

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Thus, Applicants respectfully submit that the Examiner has failed to present a *prima facie* case of obviousness, and respectfully request that the rejection under 35 U.S.C. §103 be reconsidered and withdrawn.

## Request for Rejoinder

Claims 1, 3-28, and 30-49 recite methods of using a device as recited, for example, in claims 50 and/or 78. Specifically, independent claims 1, 20, 26, 28, and 47 recite language from independent claims 50 and 78. Upon an indication of claim 50 or 78 being allowable, Applicants respectfully request that the method claims (e.g., claims 1, 3-28, and 30-49) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. See, for example, In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fec. Cir. 1995) and In re Brower, 77 F.3d 422, 37 USPQ2d 1663 (Fed. Cir. 1996).

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# **Summary**

It is respectfully submitted that all the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for PARTHASARTHY et al.

Ву

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 264 day of October, 2004, at 1/13 p.m. (Central Time).

By: Rachel Garling G. - Clark